### Message

From: Bartow, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=913B98AFDCE943E8A0E16ABA7AFF483F-SUSAN BARTOW]

**Sent**: 11/24/2021 3:32:09 PM

To: Gavin, Quinn [Gavin.Quinn@epa.gov]
Subject: RE: question about treated seeds

Thanks for sending. It is interesting to hear how other countries are dealing with treated seeds.

The article that Linda forwarded this morning provided some information about the EU too which I also thought was interesting ("banning neonicotinoid and seed coated with the pesticide altogether — something the European Union imposed in 2013.")

From: Gavin, Quinn <Gavin.Quinn@epa.gov>
Sent: Wednesday, November 24, 2021 10:06 AM

To: Bartow, Susan <Bartow.Susan@epa.gov>; Arrington, Linda <Arrington.Linda@epa.gov>; Javier, Julie

<Javier.Julie@epa.gov>; Muhammad, Maryam K. <Muhammad.Maryam@epa.gov>

Subject: FW: question about treated seeds

Hello Treated Seed Team,

Below is an email chain about Canada's policy on treated articles for importation. Essentially most treated articles just need the active ingredient registered in Canada instead of the actual product being registered. Currently seeds do not fall under that same ruling and need the specific product to be registered in Canada but they are now working on aligning their treated seed policy to match the rest of the treated articles.

Best, Quinn

From: Aranda, Amber <a randa.amber@epa.gov>
Sent: Wednesday, November 24, 2021 8:31 AM

To: Gavin, Quinn < Gavin.Quinn@epa.gov>; Arrington, Linda < Arrington.Linda@epa.gov>

Subject: FW: question about treated seeds

Hey Quinn and Linda -

While investigating how Canada is implementing its version of the treated article exemption in terms of whether it requires registration of the pesticide *product* not just the active ingredient (it only requires that the active ingredient in the used pesticide product be registered in Canada), I learned that Canada is also going to be aligning its treated seed policy consistent with that treated seed guidance. See the email chain below. **Deliberative Process / Ex. 5** 

## Deliberative Process / Ex. 5

Amber L. Aranda Environmental Protection Agency Office of General Counsel 202) 564-1737

From: Chaulk, Dana (HC/SC) < dana.chaulk@hc-sc.gc.ca>

Sent: Tuesday, November 23, 2021 9:08 AM

**To:** Aranda, Amber <aranda.amber@epa.gov> **Subject:** RE: question about treated seeds

Hi Amber,

Currently, the guidance is not the same for treated seeds. The guidance has been that the seed must be treated with a registered Canadian product. We will likely be consulting on treated seeds sometime soon, in order to align with treated articles.

Thanks! Dana

From: Aranda, Amber <aranda.amber@epa.gov>

Sent: 2021-11-22 4:08 PM

To: Chaulk, Dana (HC/SC) < dana.chaulk@hc-sc.gc.ca>

Subject: RE: question about treated seeds

Dana - One follow up question. Do you know if the guidance below also applies to treated seed?

Amber L. Aranda Environmental Protection Agency Office of General Counsel 202) 564-1737

From: Chaulk, Dana (HC/SC) < dana.chaulk@hc-sc.gc.ca>

**Sent:** Monday, November 15, 2021 2:13 PM **To:** Aranda, Amber <a href="mailto:aranda.amber@epa.gov">aranda.amber@epa.gov</a> **Subject:** RE: question about treated seeds

Hi again,

I think you specifically meant one section of guidance... I am including what we have published.

# What is required of manufacturers and importers of articles treated with an antimicrobial preservative?

Manufacturers treating articles with antimicrobial preservatives in Canada are required to use an active ingredient(s) and an end-use product(s) that are registered under the *Pest Control Products Act* for that use and within the range of approved rates.

For imported articles treated with antimicrobial preservative(s), the end-use product used to treat the article (in the foreign jurisdiction) does not require registration in Canada, but that end-use product must contain an active ingredient(s) that is (are) also registered under the *Pest Control Products Act* in Canada for that same use and the articles must be treated within the range of rates approved in Canada.

This requirement applies to treated articles whether label claims are being made or not.

Dana

From: Aranda, Amber <aranda.amber@epa.gov>

Sent: 2021-11-15 2:04 PM

To: Chaulk, Dana (HC/SC) <dana.chaulk@hc-sc.gc.ca>

Cc: Hancey, Jordan (HC/SC) <jordan.hancey@hc-sc.gc.ca>; Kivi, Michelle (HC/SC) <michelle.kivi@hc-sc.gc.ca>

Subject: RE: question about treated seeds

Actually Dana, is there a separate link to the guidance you mention in your email? I thought there might be a link to a guidance document in the link to the note below, but I don't see it there.

Amber L. Aranda Environmental Protection Agency Office of General Counsel 202) 564-1737

From: Chaulk, Dana (HC/SC) < dana.chaulk@hc-sc.gc.ca>

**Sent:** Monday, November 15, 2021 1:24 PM **To:** Aranda, Amber <a href="mailto:aranda.amber@epa.gov">aranda.amber@epa.gov</a>>

Cc: Hancey, Jordan (HC/SC) < jordan.hancey@hc-sc.gc.ca>; Kivi, Michelle (HC/SC) < michelle.kivi@hc-sc.gc.ca>

Subject: RE: question about treated seeds

Hello Amber,

Thank you for your question below. My name is Dana Chaulk and I am with the policy group of PMRA. I am the treated articles policy contact and would be happy to provide some information and hope to answer your question.

Health Canada published the <u>treated articles information note</u> in 2018 (updated in 2020) which explains Canada's regulatory requirements for articles that have been intentionally treated with a pesticide. The information note lays out the conditions that would allow an article treated with an antimicrobial to be exempt from registration under the PCPA (similar to the <u>FIFRA exemption</u>).

In Canada, an antimicrobial treated article does not require the registration of the article itself if the following conditions have been met:

- The antimicrobial preservative used to treat the article is registered under the PCPA;
- The use is limited to preventing degradation or damage to the product from microorganisms; and
- The article is treated according to the antimicrobial preservative's approved uses (in other words, the same use specified on the label of the registered end-use product) and within the registered range of rates.

We have also provided additional guidance on what is expected for imported treated articles, stating that the end-use product used in the foreign jurisdiction does not require registration in Canada, but must contain an active ingredient(s) that is (are) registered under the Pest Control Products Act for that same use and within the Canadian approved range of rates. If the treatment were to take place outside of Canada, we did not feel it would be reasonable to expect that a Canadian registered product was to be used (i.e., USA laws would required a product used in the USA to be registered by the US EPA). By requiring that the active be registered in Canada for that use (essentially there is at least one end-use product registered in Canada for that treatment) would mean less barriers to trade, while still having confidence that the product used for the treatment would meet the Canadian requirements for a safe and effective treated end-use product.

You asked what the real world implications have been. We published the treated articles information note to educate our stakeholders and broaden the reach of our message. Prior to the publication we were communicating specifics for treated articles on a case by case bases. We had hoped the publication, along with our webinar and stakeholder outreach, would lead to an increase in active registrations in Canada, so that imported treated articles would be brought into compliance (there are products on Canadian shelves which contain active ingredients that are not yet registered in Canada for that use). We have not seen an influx of applications for registration of new antimicrobial registrations. We continue to work with out stakeholders to continue educating them on what the importation requirements are.

Happy to have a call if you wish further details on any of the above.

Thank you,

Dana Chaulk (she/elle)
Senior Policy Analyst/ Analyste principale des politiques

Pest Management Regulatory Agency, Health Canada dana.chaulk@hc-sc.gc.ca, 343-540-9858

Agence de réglementation de la lutte antiparasitaire, Santé Canada dana.chaulk@hc-sc.gc.ca, 343-540-9858

From: Aranda, Amber <aranda.amber@epa.gov>

Sent: 2021-11-10 4:35 PM

To: Hancey, Jordan (HC/SC) <<u>iordan.hancey@hc-sc.gc.ca</u>>; Girard, Stephanie (HC/SC) <<u>stephanie.girard@hc-sc.gc.ca</u>>
Cc: Hopkins, Yvette <<u>Hopkins.Yvette@epa.gov</u>>; Chaulk, Dana (HC/SC) <<u>dana.chaulk@hc-sc.gc.ca</u>>; Kivi, Michelle (HC/SC) <<u>michelle.kivi@hc-sc.gc.ca</u>>; Zhu, Yibin (HC/SC) <<u>yibin.zhu@hc-sc.gc.ca</u>>; De Jong, John (HC/SC) <<u>john.dejong@hc-sc.gc.ca</u>>; Ramos, Julie (HC/SC) <<u>julie.ramos@hc-sc.gc.ca</u>>

Subject: RE: question about treated seeds

Thank you again!

Amber L. Aranda Environmental Protection Agency Office of General Counsel 202) 564-1737

From: Hancey, Jordan (HC/SC) < jordan.hancey@hc-sc.gc.ca>

Sent: Wednesday, November 10, 2021 2:45 PM

To: Aranda, Amber <aranda.amber@epa.gov>; Girard, Stephanie (HC/SC) <stephanie.girard@hc-sc.gc.ca>
Cc: Hopkins, Yvette <<u>Hopkins.Yvette@epa.gov</u>>; Chaulk, Dana (HC/SC) <<u>dana.chaulk@hc-sc.gc.ca</u>>; Kivi, Michelle (HC/SC) <<u>michelle.kivi@hc-sc.gc.ca</u>>; Zhu, Yibin (HC/SC) <<u>yibin.zhu@hc-sc.gc.ca</u>>; De Jong, John (HC/SC) <<u>john.dejong@hc-</u>

sc.gc.ca>; Ramos, Julie (HC/SC) <julie.ramos@hc-sc.gc.ca>

Subject: RE: question about treated seeds

Amber,

Further to the below, we have started reviewing your question and hope to get back to you soon. We will also follow up if we have questions for clarification.

Thanks!

Jordan

From: Aranda, Amber <aranda.amber@epa.gov>

Sent: 2021-11-10 2:23 PM

To: Girard, Stephanie (HC/SC) < stephanie.girard@hc-sc.gc.ca>

Cc: Hopkins, Yvette < Hopkins. Yvette@epa.gov>; Hancey, Jordan (HC/SC) < jordan.hancey@hc-sc.gc.ca>

Subject: RE: question about treated seeds

Thank you!

Amber L. Aranda Environmental Protection Agency Office of General Counsel 202) 564-1737

From: Girard, Stephanie (HC/SC) < <a href="mailto:stephanie.girard@hc-sc.gc.ca">stephanie.girard@hc-sc.gc.ca</a>

**Sent:** Wednesday, November 10, 2021 2:19 PM **To:** Aranda, Amber <aranda.amber@epa.gov>

Cc: Hopkins, Yvette < Hopkins. Yvette@epa.gov>; Hancey, Jordan (HC/SC) < jordan.hancey@hc-sc.gc.ca>

Subject: Re: question about treated seeds

### Hello

Thank you for your question. I will refer you to our director of policy, Jordan Hancey (<u>jordan.hancey@hc-sc.gc.ca</u>) His group has been working on this topic. He is also copied on this email Best regards

Sent from my iPhone

\_\_\_\_\_\_

Stéphanie Girard PMRA / ARLA

Health Canada / Santé Canada

Email: <u>stephanie.girard@canada.ca</u> / Tel: 613-736-3394, **cell**: 613-297-1742

Le 9 nov. 2021 à 08:10, Aranda, Amber <aranda.amber@epa.gov> a écrit :

Yvette - Thank you for connecting us.

Stephanie – A question has been raised as to whether the U.S. approach for exempting treated articles from FIFRA registration requires that the pesticide product be registered in the U.S. for the article use or allows any pesticide product to be used as longs as the active ingredient in that product is one that is registered in the U.S. for that use. (This impacts treated articles generally not just treated seed.) It appears the question relates to concerns that U.S. registered pesticide products may not be used/dual registered in other countries that may be exporting to the U.S. articles treated with pesticides, and thus if taking an active ingredient interpretation, imports will stop and/or EPA will be inundated with

requests for registration of treated articles. In looking at EU and Canada materials on treated articles and the U.S.-Canada Harmonization materials on treated seed, the documents seem to be just shy of explicitly stating that the actual product used to treat the article must itself be registered. I'm hoping to confirm with you which approach is used in Canada, and what the real world implications have been. For example, if the pesticide product used must be registered in Canada for the treated product to be covered by Canada's exemption, have foreign entities sought a Canadian registration for use in another country to be able to import treated articles or is Canada registering treated articles imported? If it would help to discuss the issues, we can schedule a call. Thank you for your thoughts and attention to the question.

Amber L. Aranda Environmental Protection Agency Office of General Counsel 202) 564-1737

From: Hopkins, Yvette < Hopkins. Yvette@epa.gov>

Sent: Monday, November 8, 2021 7:41 PM

To: stephanie.girard@hc-sc.gc.ca

Cc: Aranda, Amber <aranda.amber@epa.gov>
Subject: FW: question about treated seeds

Stephanie,

I understand you have recently taken over on these treated seed issues, but there are several points that our Agency is trying to clarify regarding the Treated Articles Exemption. I am copying Amber from our Office of General Counsel who has some specific questions.

Yvette Hopkins

FIFRA Enforcement Coordinator/Device Determination Co-Chair/ Senior State Liaison Office of Chemical Safety and Pollution Prevention, US EPA

Office: 703 308-1090 Cell: 571 289-6676

"Ignorance allied with power is the most ferocious enemy of justice." James Baldwin

From: Isbell, Diane < <a href="mailto:lsbell.Diane@epa.gov">lsbell, Diane@epa.gov</a>>
Sent: Monday, November 8, 2021 1:21 PM

To: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>

Cc: Hopkins, Yvette < Hopkins. Yvette@epa.gov >; Girard, Stephanie (HC/SC) < stephanie.girard@hc-

sc.gc.ca>

Subject: RE: question about treated seeds

Thanks so much Minoli! I don't look forward to going back into the office. Of course we are moving from Arlington to DC!!

Wow, I didn't know that Martha retired. That is great!

Diane Isbell
Ombudsman/Senior Advisor
Antimicrobials Division
Office of Pesticide Programs

### U.S. Environmental Protection Agency

www.epa.gov/pesticides

From: Silva, Minoli (HC/SC) <minoli.silva@hc-sc.gc.ca>

Cc: Hopkins, Yvette < Hopkins. Yvette@epa.gov >; Girard, Stephanie (HC/SC) < stephanie.girard@hc-

sc.gc.ca>

Subject: RE: question about treated seeds

Hi Diane

Its not much different here.

I am actually thinking of going back into the office on a regular basis – how crazy is that © I have cc'd Stephanie Girard as she took over as Fred (Chief Registrar)'s advisor when Martha retired. Martha was very involved with treated seed. Stephanie is just getting up to speed on this subject but will be able to point you in the right direction at least.

Best

Minoli

Minoli Silva

Director | Directrice

Review and Science Integration Division | Division des examens et de l'intégration scientifique Pest Management Regulatory Agency | Agence règlementaire de la lutte antiparasitaire

Health Canada | Santé Canada

Minoli.Silva@canada.ca

Telephone | Téléphone: 613-769-3406

From: Isbell, Diane < Isbell.Diane@epa.gov>

**Sent:** 2021-11-08 11:58 AM

**To:** Silva, Minoli (HC/SC) < <a href="minoli.silva@hc-sc.gc.ca">minoli.silva@hc-sc.gc.ca</a> <a href="minoli.silva@hc-sc.gc.ca">Cc: Hopkins, Yvette <a href="minoli.silva@hc-sc.gc.ca">Hopkins, Yvette@epa.gov</a> <a href="minoli.silva@hc-sc.gc.ca">No. 10 | No. 10 |

Subject: question about treated seeds

Hi Minoli,

I hope that you are well! I am fine – we are still dealing with crazy pandemic issues. I think it is a bit better but that isn't saying much.

One of our attorneys has questions about how Canada handles treated seeds. Who would be a good person for her to talk with? I have copied Yvette Hopkins, as I am out of the office this week. Thanks! Diane

Diane Isbell
Ombudsman/Senior Advisor
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
www.epa.gov/pesticides